

TELZIR

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I taking TELZIR?

TELZIR contains the active ingredient fosamprenavir which belongs to a group of antiretroviral medicines called protease inhibitors. TELZIR is taken with ritonavir and is used to slow down the progression of human immunodeficiency virus (HIV) infection which can lead to Acquired Immune Deficiency Syndrome (AIDS) and other related illnesses (e.g. AIDS-related Complex (ARC)).

For more information, see Section [1. Why am I taking TELZIR?](#) in the full CMI.

2. What should I know before I use TELZIR?

Do not use if you have ever had an allergic or hypersensitivity reaction to fosamprenavir, amprenavir, ritonavir or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I take TELZIR?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TELZIR and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take TELZIR?

- Adults over the age of 18 in treatment-naïve patients: the dose is 1400 mg (two tablets) once a day with 200 mg ritonavir once a day or 700 mg (one tablet) twice a day with 100 mg ritonavir twice a day.
- Adults over the age of 18 in protease inhibitor experienced patients: the dose is 700 mg (one tablet) with 100 mg ritonavir twice a day in combination with other antiretroviral agents.
- In children and adolescents between 6 and 18: 700 mg (one tablet) twice a day plus 100 mg ritonavir twice a day.

More instructions can be found in Section [4. How do I take TELZIR?](#) in the full CMI.

5. What should I know while using TELZIR?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking TELZIR.• Have blood tests when you are meant to so your doctor can check for side effects.• Keep in contact with your doctor and don't stop taking TELZIR without talking to your doctor.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly or change the dose without talking to your doctor.• Do not take this medicine to treat any other complaints.
Driving or using machines	<ul style="list-style-type: none">• TELZIR can make you dizzy and have other side effects that make you less alert.• Do not drive or use a machine unless you

	are sure you are not affected.
Looking after your medicine	<ul style="list-style-type: none"> • Store TELZIR below 30°C in the pack. • Keep your tablets in the bottle until it is time to take them.

For more information, see Section [5. What should I know while using TELZIR?](#) in the full CMI.

6. Are there any side effects?

Side effects that have been reported include: nausea, vomiting, diarrhoea, flatulence, abdominal pain, headache, rash, fatigue, feeling tired, an altered sensation in your mouth, dizziness, muscle pain, tenderness and weakness.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

TELZIR

Active ingredient(s): fosamprenavir

Consumer Medicine Information (CMI)

This leaflet provides important information about using TELZIR. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using TELZIR.**

Where to find information in this leaflet:

- [1. Why am I taking TELZIR?](#)
- [2. What should I know before I take TELZIR?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take TELZIR?](#)
- [5. What should I know while taking TELZIR?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking TELZIR?

TELZIR contains the active ingredient fosamprenavir. TELZIR belongs to a group of antiretroviral medicines called protease inhibitors.

TELZIR is taken with another HIV medicine called ritonavir and is used to slow down the progression of human immunodeficiency virus (HIV) infection

which can lead to Acquired Immune Deficiency Syndrome (AIDS) and other related illnesses (e.g. AIDS-related Complex (ARC)).

The low doses of ritonavir you take together with TELZIR are designed to increase the amount of the active ingredient, amprenavir, available to control your HIV infection.

TELZIR does not cure AIDS or HIV infection however it slows down production of HIV in the body. In this way it stops ongoing damage to the body's immune system which fights infection.

You can still pass on HIV when taking this medicine through sexual activity or through passing on blood or bodily secretions which carry the HIV virus, although the risk is lowered by taking antiretroviral therapy.

You should use proper precautions to prevent this from occurring. Discuss with your doctor the precautions needed to avoid infecting other people.

While taking TELZIR and/or any other therapy for HIV, you may continue to develop other infections and other complications of HIV infection. You should keep in regular contact with your doctor.

It is important to read the patient information relating to ritonavir before you start taking this medicine. Ask your doctor or pharmacist for a copy.

2. What should I know before I take TELZIR?

Warnings

Do not use TELZIR if:

- you are allergic or had a hypersensitivity reaction to fosamprenavir, amprenavir, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

- you are allergic to ritonavir or any of the ingredients in that medicine
- you are pregnant, trying to become pregnant or are breastfeeding
- you are taking any of the following medicines: astemizole, terfenadine, rifampicin, telaprevir, boceprevir, simeprevir, paritaprevir, midazolam, triazolam, sildenafil, dihydroergotamine, ergotamine, cisapride, pimozide, quetiapine, lurasidone, flecainide, propafenone, St John's Wort

Check with your doctor if you:

- have any other medical conditions
- are allergic to food, dyes, preservatives or any other medicines (eg sulfonamide)
- have diabetes mellitus or haemophilia

- have or have ever had any liver problems, for example jaundice, hepatitis, a virus affecting your liver, an enlarged liver or liver scarring (cirrhosis)

If you have liver disease you will need to have your dose of TELZIR and/or ritonavir adjusted. It is not possible to reduce the dose of TELZIR tablets to less than 700 mg, so people with moderate or severe liver disease must not be treated with TELZIR tablets. If you are unsure about your level of liver disease consult your doctor who may carry out additional testing to see whether the TELZIR/ritonavir combination is suitable for you.

- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Talk to your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor will discuss with you the risks and benefits involved of using TELZIR with ritonavir whilst pregnant or breastfeeding.

If you are taking the contraceptive pill, it is recommended that you use an alternative method of contraception (e.g. a condom) to prevent pregnancy while you are taking TELZIR.

Symptoms of infection and inflammation

People with advanced HIV infection (AIDS) have weak immune systems and are more likely to develop serious infections (opportunistic infections). When they start treatment, the immune system becomes stronger and so the body starts to fight infections.

Symptoms of infection and inflammation may develop, caused by either:

- old, hidden infections flaring up as the body fights them
- the immune system attacking healthy body tissue (autoimmune disorders)

The symptoms of autoimmune disorders may develop many months after you start taking medications to treat your HIV infection.

Symptoms may include:

- muscle weakness and/or muscle pain
- joint pain or swelling
- weakness beginning in the hands or feet and moving towards the trunk of the body
- palpitations or tremor
- hyperactivity (excessive restlessness and movement)

If you get symptoms of infection or if you notice any of the symptoms above, tell your doctor immediately. Do not take other medicines for the infection without your doctor's advice.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

The following medicines can interact with TELZIR and ritonavir and must not be taken with TELZIR and ritonavir:

- astemizole and terfenadine, which are used to treat hayfever
- rifampicin, used to treat tuberculosis
- telaprevir, boceprevir, simeprevir, paritaprevir and similar medicines used to treat hepatitis C
- nevirapine, a medicine used to treat HIV
- midazolam and triazolam, medicines which induce sedation
- sildenafil when it is used to treat increased pressure in the blood vessels to your lungs
- dihydroergotamine and ergotamine which are used to treat migraine
- cisapride which is used to treat gastric reflux
- pimozide which is used to treat chronic psychotic disorders
- alfuzosin, a medicine used in men to treat benign prostatic hyperplasia
- quetiapine, a medicine used to treat schizophrenia, bipolar disorder and major depressive disorder

- lurasidone, a medicine used to treat schizophrenia and bipolar disorder
- flecainide which is used to treat heart conditions
- propafenone which is used to treat heart conditions
- herbal treatments such as St Johns Wort

TELZIR and ritonavir may interact with certain other medications. The use of these medicines, together with the TELZIR/ritonavir combination, should only take place on the basis of medical advice which may include monitoring decreased medicine effects, monitoring your blood and decreasing dosages:

- antibiotics such as rifabutin, clarithromycin, dapson and erythromycin
- antifungals including ketoconazole, itraconazole
- halofantrine, an antimalarial medicine
- benzodiazepines such as alprazolam and clorazepam
- calcium channel blockers such as diltiazem, nifedipine, nifedipine, nimodipine, felodipine, verapamil, amlodipine, and isradipine
- medicines used to lower your cholesterol including atorvastatin, lovastatin and simvastatin
- erectile dysfunction medicines including sildenafil, tadalafil, vardenafil
- non-nucleoside reverse transcriptase inhibitors such as efavirenz, nevirapine and delavirdine
- opioids, for example methadone
- steroids such as oestrogens, progestogens and some glucocorticoids
- inhaled/nasal steroid including fluticasone

- immunosuppressants and medicines used to suppress your immune system such as ciclosporin, tacrolimus
- clozapine, an antipsychotic medicine
- carbamazepine, a medicine used to in seizures
- famotidine, nizatidine, ranitidine, cimetidine, medicines used to decrease stomach acid production
- paroxetine, a medicine used to treat depression
- loratadine, a medicine used to treat hayfever
- maraviroc and dolutegravir, medicines used to treat HIV
- medications used to treat several types of cancers such as dasatinib, nilotinib, ibrutinib, vinblastine and everolimus

If you are taking certain medicines that can cause serious side effects, such as amiodarone, phenobarbitone, phenytoin, lidocaine, tricyclic antidepressants, quinidine and warfarin, at the same time as you are taking the TELZIR/ritonavir combination, your doctor may carry out additional blood tests to minimise any potential safety problems.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect TELZIR.

4. How do I take TELZIR?

How much to take

Adults over the age of 18:

- Treatment-naïve patients: the dose of TELZIR is 1400 mg (two tablets) once a day with 200 mg ritonavir once a day or 700 mg (one tablet) twice a day with 100 mg ritonavir twice a day
- Protease inhibitor experienced patients: the recommended dose is 700 mg (one tablet) with 100 mg ritonavir twice a day in combination with other antiretroviral agents. The once daily administration of TELZIR plus ritonavir is not recommended in protease inhibitor experienced patients.

Children and adolescents between 6 and 18 years of age:

- If the child weighs over 39 kg and can swallow the tablets whole then the adult dosing regimen of 700 mg (one tablet) twice a day plus 100 mg ritonavir twice a day can be used. Ritonavir 100 mg capsules can be used by children and adolescents who weigh more than 33 kg and can swallow the capsules whole.

The use of TELZIR in combination with ritonavir has not been established in children less than 6 years of age.

Follow the instructions provided and use TELZIR until your doctor tells you to stop.

How to take TELZIR

- Swallow the tablets whole with a glass of water.
- You can take TELZIR with or without food.

If you forget to take TELZIR

TELZIR should be used regularly at the same time each day.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you take too much TELZIR

If you think that you have used too much TELZIR, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking TELZIR?

Things you should do

Tell your doctor straight away if you:

- become pregnant or intend to become pregnant
- have not taken TELZIR as intended

Remind any doctor, dentist or pharmacist you visit that you are taking TELZIR.

Stay in regular contact with your doctor

TELZIR helps to control your condition, but it is not a cure for HIV infection. You need to keep taking it every day to stop your illness from getting worse. Because TELZIR does not cure HIV infections, you may still develop other infections and illnesses linked to HIV.

Things you should not do

- Do not stop taking this medicine suddenly or change the dose.
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.
- Do not use this medicine to treat any other complaints unless your doctor tells you to.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how TELZIR affects you.

Looking after your medicine

Follow the instructions on the pack on how to take care of your medicine properly.

Store it in a cool dry place (below 30°C) away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Within the first few weeks of treatment with anti-HIV medicines, some people, particularly those that have been HIV positive for some time, may develop inflammatory reactions (e.g. pain, redness, swelling, high

temperature) which may resemble an infection and may be severe. It is thought that these reactions are caused by a recovery in the body's ability to fight infections, previously suppressed by HIV.

If you become concerned about any new symptoms, or any changes in your health after starting HIV treatment, discuss with your doctor immediately.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p data-bbox="204 1055 571 1099">Gastrointestinal</p> <ul data-bbox="204 1137 614 1391" style="list-style-type: none"><li data-bbox="204 1137 614 1189">● nausea, vomiting<li data-bbox="204 1205 454 1256">● diarrhoea<li data-bbox="204 1272 454 1323">● flatulence<li data-bbox="204 1339 576 1391">● abdominal pain <p data-bbox="204 1442 384 1487">General</p> <ul data-bbox="204 1525 774 1832" style="list-style-type: none"><li data-bbox="204 1525 454 1576">● headache<li data-bbox="204 1592 391 1644">● fatigue<li data-bbox="204 1659 774 1765">● altered sensation in your mouth<li data-bbox="204 1780 454 1832">● dizziness <p data-bbox="204 1883 475 1928">Skin related</p> <ul data-bbox="204 1966 343 2018" style="list-style-type: none"><li data-bbox="204 1966 343 2018">● rash	<p data-bbox="810 1055 1369 1272">Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<p>Occasionally the skin rash may be severe and as a result your doctor may decide that you have to stop taking this medicine</p> <p>Musculoskeletal:</p> <ul style="list-style-type: none"> ● muscle pain ● tenderness and weakness <p>These side effects have been reported with antiretroviral therapy including protease inhibitors and nucleoside analogues.</p>	

In some individuals, treatment with a combination of antiretroviral medicines that includes a protease inhibitor may find their body shape changes due to an increase in body fat. It is not yet known what causes these changes, or whether they have any long-term effects on your health. If you notice changes in your body shape, speak to your doctor.

Your doctor will ask you to undertake blood tests regularly to monitor for any abnormalities (blood lipids and blood sugar). Increases in liver enzymes and blood fats have been reported in patients taking TELZIR and ritonavir.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What TELZIR contains

Active ingredient (main ingredient)	Fosamprenavir as fosamprenavir sodium
Other ingredients (inactive ingredients)	croscarmellose sodium colloidal silicon dioxide

	<p>magnesium stearate</p> <p>microcrystalline cellulose</p> <p>povidone K30</p> <p>The tablet coating contains:</p> <p>glycerol triacetate</p> <p>hypromellose</p> <p>iron oxide red (E172)</p> <p>titanium dioxide (E171)</p>
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Do not take this medicine if you are allergic to any of these ingredients.

What TELZIR looks like

TELZIR tablets are pink, film-coated, capsule-shaped, biconvex tablets, debossed GX LL7 on one face (AUST R 101604). They are available in bottles of 60 tablets.

Who distributes TELZIR

ViiV Healthcare Pty Ltd

Level 4, 436 Johnson Street

Abbotsford VIC 3067

Australia

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MA 02139 USA.

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